UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,672	04/02/2001	Nabil Hanna	P 0280062 2000-30-0178A	9345

909 7590 06/25/2002

PILLSBURY WINTHROP, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/822,672	Applicant(s) HANNA, NABIL	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 18-21, 24 drawn to a method of avoiding, decreasing, or overcoming the resistance of hematologic malignant cells comprising administering an anti-cytokine antibody, classified in class 424, subclass 156.1.

II. Claims 15-17, drawn to a kit comprising an antibody, classified in class 530, subclass 387.1.

III. Claim 22, drawn to a method of treating a patient who has relapsed following chemotherapy, classified in class 424, subclass 156.1.

IV. Claim 23, 26, drawn to a method of treating a patient who is refractory to chemotherapy, classified in class 424, subclass 156.1.

V. Claim 25 and 28, drawn to a method for treating a patient who has relapsed following therapy, classified in class 424, subclass 130.1.

VI. Claim 29-47, drawn to a method of treating a B cell lymphoma comprising administering a B-cell depleting antibody and an anti-cytokine antibody, classified in class 424, subclass 152.1.

VII. Claim 50-56, 58-71, 75 drawn to a method of treating a tumor comprising administering an antibody specific to a cytokine and a B cell depleting antibody, classified in class 424, subclass 155.1

VIII. Claim 57, drawn to a kit comprising an anti-CD20 antibody and a anti-cytokine antibody, classified in class 530, subclass 387.1.

IX. Claims 72 and 73, drawn to a method of treating a B cell lymphoma with an anti-IL-10 antibody, classified in class 424, subclass 156.1.

X. Claims 74-75, drawn to a method of treating B cell lymphoma with an anti-IL-10 antibody and a B cell depleting antibody, classified in class 424, subclass 156.1.

XI. Claims 76-82 drawn to a method of treating non-Hodgkin's lymphoma with an anti-IL-10 antibody and an antiCD20 or CD22 antibody, classified in class 424, subclass 156.1.

XII. Claims 83-86 drawn to a method of treating lymphoma with an anti-IL-10 antibody and a antiCD20 antibody and chemotherapy, classified in class 424, subclass 156.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups II and VIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The anti-cytokine antibody of Group II and the anti-cytokine and anti-CD20 antibody of Group VIII are all structurally and chemically different from each other. The antibodies bind to separate and distinct cytokines and art on one antibody to one cytokine would not necessarily be art on another. The examination of all groups would require different

searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions II and VIII are patentably distinct.

The methods of Inventions I, III-VII, and IX-XII and IV-VII differ in the method objectives, method steps and parameters and in the reagents used. Invention I recites a method of avoiding, decreasing, or overcoming the resistance of hematologic malignant cells comprising administering an anti-cytokine antibody; Invention III recites a method of treating a patient who has relapsed following chemotherapy; Invention IV recites a method of treating a patient who is refractory to chemotherapy; Invention V recite a method for treating a patient who has relapsed following therapy; Invention VI recites a method of treating a B cell lymphoma comprising administering a B-cell depleting antibody and an anti-cytokine antibody; Invention VII recites and Invention VII recites a method of treating a tumor comprising administering an antibody specific to a cytokine and a B cell depleting antibody; Invention IX recites a method of treating a B cell lymphoma with an anti-IL-10 antibody; Invention X recites a method of treating B cell lymphoma with an anti-IL-10 antibody and a B cell depleting antibody; Invention XI recites a method of treating non-Hodgkin's lymphoma with an anti-IL-10 antibody and an antiCD20 or CD22 antibody and Invention XII recites a method of treating lymphoma with an anti-IL-10 antibody and a antiCD20 antibody and chemotherapy. . The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability

issues. Thus Inventions I, III-VII, and IX-XII and IV-VII differ in the method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions II, VIII and I, III-VII, IX-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Groups II and VIII can be used in a materially different method such as to purify the antigen in addition to the methods listed in Groups I, III-VII, and IX-XII.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: If any of Groups I-V are elected then applicant must elect one of the following:

Species A IL-2

Species B IL-6

Species C IL-10

Species D TNF-alpha

If any of Groups VI-VII are elected then applicant must elect one of species A-D and one of the following

Species E anti-CD20

Species F anti-CD19

Species G anti-CD22

Species H anti-CD23

Species I anti-CD27

Species J anti-CD37

Species K anti-CD53

Species L anti-CD72

Species M anti-CD73

Species N anti-CD74

Species O anti-CD78

Species P anti-CD79a

Species Q anti-CD79b

Species R anti-CD80

Species S anti-CD81

Species T anti-CD82

Species U anti-CD83

Species V anti-CDw84

Species W anti-CD85

Species X anti-CD86

The species listed above are distinct because art on one antibody would not necessarily be art on another. In addition each antibody binds a distinct antigen.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

34. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter and different classifications, restriction for examination purposes as indicated is proper.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
Larry R. Helms Ph.D.
703-306-5879

Sheela Huff

SHEELA HUFF
PRIMARY EXAMINER